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(54) Title: TISSUE ACQUISITION DEVICE AND METHOD

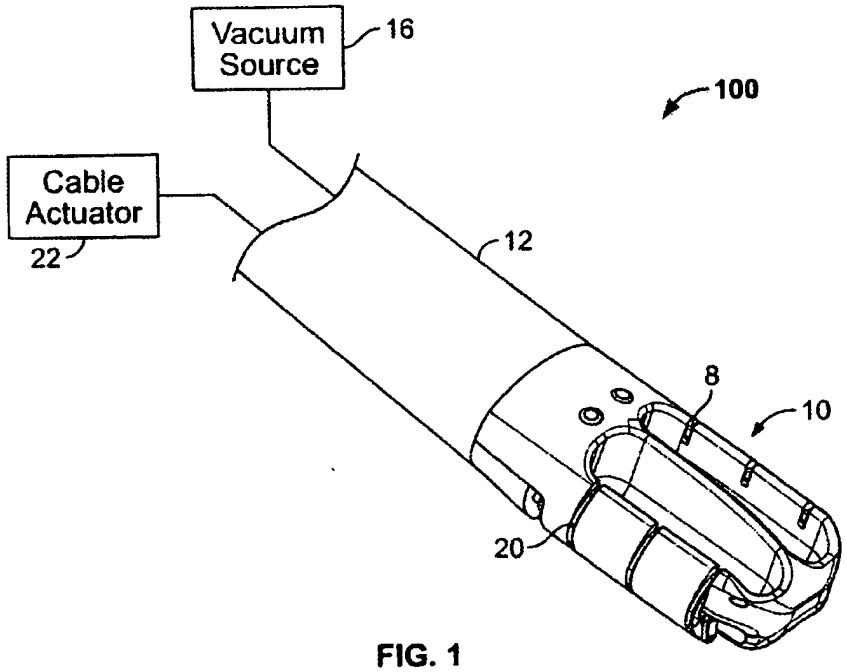


FIG. 1

(57) Abstract: A device and method for acquiring tissue from remote regions of a hollow internal organ, such as the stomach, in preparation for tissue fastening, is disclosed. The device includes (a) an acquisition head defining first and second side-by-side tissue-acquisition chambers, (b) a vacuum channel communicating with each of said chambers, through which a vacuum may be independently applied to the first and second chambers, and a retention element for retaining tissue captured in a chamber. The device allows tissue regions, e.g., folds, to be independently captured and placed in a side-by-side configuration for stapling.

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# TISSUE ACQUISITION DEVICE AND METHOD

## FIELD OF THE INVENTION

[001] The present invention relates to a device and method for acquiring tissue within a hollow organ such as the stomach, for purposes of fastening the acquired regions and/or reconfiguring the organ.

## BACKGROUND OF THE INVENTION

[002] Surgical procedures used to modify the shape and/or size of a stomach are effective in reducing weight and resolving associated co morbidities. Unfortunately these surgical procedures are invasive and are associated with high levels of peri-operative and post operative complications.

[003] Some procedures have been introduced which utilize natural body orifices for surgery to reduce the invasiveness of these procedures. Natural orifices include, but are not limited to the esophagus, anus and vagina. These procedures are less invasive by nature but have limitations as will be described below.

[004] Natural orifice procedures have largely been directed at the gastrointestinal (GI) tract, but also include procedures which exit the GI tract, and perform surgeries normally done laparoscopically. Access to the peritoneal space for example can be accomplished by penetrating the stomach wall.

[005] One primary means of stomach modification is by the use of surgical or laparoscopic staplers. These devices are able to surgically or laparoscopically appose multiple layers of tissue and connect them by use of multiple staple rows. Early procedures stapled across the outside of the stomach, which brought the mucosa of two sides of the stomach into apposition. There was, and is, a high rate of failure of these staple lines due to the nature of the GI tract. Staple line dehiscence was common and resulted in inadequate clinical results. The solution was to surgically staple the tissue and cut between the staple lines. This enabled edge to edge healing to occur, and provided for a robust tissue bridge. The separation/cutting of tissues is now common for surgical procedures such as Roux-En-Y Gastric Bypass, Sleeve Gastrectomy, and Vertical Banded Gastroplasty. However, less invasive procedures allowing stomach partitioning using natural orifice access are highly desirable.

[006] Some existing procedures attempt to partition the stomach from the inside by connecting tissue within the stomach. To date these procedures have demonstrated a high failure rate. Improved devices and methods for creating robust stomach partitions using natural orifice access are disclosed in commonly owned U.S. Application No. 11/900,757, filed September 13, 2007, which was published as US 2008-0190989 and which is entitled ENDOSCOPIC PLICATION DEVICE AND METHOD.

[007] As described in the '757 application, when an area of the stomach wall is drawn inwardly (bringing a two-layer "pinch" or fold of tissue toward the stomach interior), corresponding regions of serosal tissue on the exterior of the stomach are positioned facing one another. The applications discloses plication procedures in which two or more such areas or pinches of the stomach wall are engaged/grasped and drawn inwardly using instruments passed into the stomach via the mouth. The two or more pinches of tissue are held in complete or partial alignment with one another as staples or other fasteners are driven through the pinches, thus forming a four-layer tissue plication. Over time, adhesions formed between the opposed serosal layers create strong bonds that can facilitate retention of the plication over extended durations, despite the forces imparted on them by stomach movement.

[008] One or more such plications may be formed for a variety of purposes. For example, plications may be used to induce weight loss by creating a barrier or narrowing within the stomach that will restrict the flow of food from the proximal stomach towards the distal stomach. For example, as discussed in the '757 application, a partition or barrier may be oriented to extend across the stomach, leaving only a narrow exit orifice through which food can flow from the proximal stomach to the distal stomach, or a similar antral barrier may be formed that will slow stomach emptying of stomach contents into the pylorus. In other cases, partitions or plications may be used to form a proximal pouch in the stomach or to reduce stomach volume to cause sensations of fullness after a patient eats relatively small quantities. Plications might also be used as a treatment for GERD to create a shield between the stomach and esophagus that will minimize reflux. Plications might also be used to close perforations in the stomach wall.

SUMMARY OF THE INVENTION

[009] The present application describes an improved tissue acquisition instrument useful for engaging areas or pinches of tissue, e.g., tissue folds, and supporting the engaged areas of tissue in complete or partial alignment as the areas are fastened to one another using fasteners, staples, sutures, or the like

[0010] The invention includes, in one aspect, a tissue acquisition device for use in acquiring tissue from remote regions within a hollow organ, for purposes fastening the acquired regions to one another. The device includes (a) an acquisition head defining first and second side-by-side tissue-acquisition chambers, (b) a vacuum channel communicating with each of said chambers, through which a vacuum may be independently applied to the first and second chambers, such that when the acquisition head is placed against a first wall region within the organ, and vacuum is applied to the first chamber, a portion of the wall region is drawn into the first chamber, (c) associated with the first chamber, a first retention element, and (d) a first linkage operatively connected to the retention element for moving the same between open and closed positions in which the retention element is positioned to allow tissue to be drawn into the chamber when a vacuum is applied thereto, and to retain tissue drawn into the chamber, when vacuum is released from the first chamber, respectively. With tissue retained in the first chamber by the retention element, the tissue acquisition device can be moved to a second tissue region within the organ to draw a second target tissue into the second chamber by application of a vacuum to the second chamber, such that the two tissue regions are configured as side-by-side tissue folds that can be fastened together.

[0011] The retention element may have fingers that in the second position may extend at least partially into the vacuum chamber to retain tissue drawn into the acquisition chamber. The retention element may be biased toward its open position, and moveable against the bias to its closed position.

[0012] The device may further include, associated with the second vacuum chamber, a second retention element, and a second linkage operatively connected to the second retention element for moving the same between open and closed positions in which the retention element is positioned to allow tissue to be drawn into the second chamber when a vacuum is applied thereto, and to retain tissue drawn into the second chamber, when vacuum is released from the

first chamber, respectively. The first and second retention elements may be independently moveable between their open and closed positions.

[0013] The acquisition device may further include an elongate flexible shaft having a proximal end and a distal end, the acquisition head being positioned on the distal end of the elongate shaft, the shaft being proportion to extend transorally in a human subject, with the distal end in a body cavity to be treated and with the proximal end external to the human subject. The shaft may carry one or more vacuum lines connected to said vacuum channels and one or more cables operatively connected to said linkages, for controlling the positions of the associated retention elements.

[0014] In another aspect, the invention includes a tissue-attachment system for use in acquiring tissue from remote regions within a hollow internal organ, for purposes fastening the acquired regions to one another. The system includes (a) an acquisition head defining first and second side-by-side tissue-acquisition chambers, (b) a vacuum channel communicating with each of said chambers, through which a vacuum may be independently applied to the first and second chambers, such that when the acquisition head is placed against a first wall region of the internal organ, and vacuum is applied to the first chamber, a portion of the wall region is drawn into the first chamber, (c) associated with the first chamber, a first retention element, (d) a first linkage operatively connected to the retention element for moving the same between open and closed positions in which the retention element is positioned to allow tissue to be drawn into the chamber when a vacuum is applied thereto, and to retain tissue drawn into the chamber, when vacuum is released from the first chamber, respectively, wherein the tissue acquisition device, with tissue retained in the first chamber by the retention element, can be moved to a second tissue region within the organ to draw a second target tissue into the second chamber by application of a vacuum to the second chamber, such that the two tissue regions are configured as side-by-side tissue folds that can be fastened together. and (e) an elongate flexible shaft having a proximal end and a distal end at which the tissue-acquisition head is carried, the shaft being proportion to extend transorally in an adult human subject, with the distal end in a body cavity to be treated and with the proximal end external to the human subject, and said shaft carrying one or more vacuum lines connected to said vacuum channels and one or more cables operatively connected to said linkages, for controlling the positions of the associated retention elements.

[0015] The system may further include a stapler for stapling together a pair of tissue folds formed by the capture of first and second tissue regions in said first and second chambers, respectively.

[0016] In still another aspect, the invention includes a method of fastening remote regions of a hollow organ to one another. The method includes of the steps of: (i) transorally accessing the interior of the organ with an acquisition head defining first and second side-by-side tissue-acquisition chambers, (ii) placing the acquisition head against a first tissue region within the hollow organ; (iii) applying a vacuum to the first, but not the second, acquisition chamber, to draw a portion of the first tissue regions into the first chamber; (iv) mechanically capturing the portion of the first tissue region in the first acquisition chamber, (v) positioning the acquisition head, with the first captured tissue portion, against a second tissue region within the hollow organ,(vi) before or after said positioning, releasing vacuum at the first acquisition chamber and applying vacuum to the second chamber, (vii) by steps (v) and (vii) drawing a portion of the second tissue region into the second tissue-acquisition chamber, (viii) mechanically capturing the portion of the second tissue region in the second acquisition chamber, wherein the two captured tissue regions form two tissue folds terminating at the acquisition device, (ix) fastening the two tissue folds together; and (x) releasing the fastened tissue folds from the acquisition device.

[0017] Mechanically capturing tissue in steps (iv) and (viii) may include moving a retention element containing a plurality of fingers into a position at which the fingers engage the tissue region within the associated acquisition chamber.

[0018] Fastening the two tissue folds together in step (ix) may include placing the folds between confronting circular faces of a staple holder and anvil and forming an annular array of staples through the two folds.

[0019] These and other objects and features of the invention will become more fully apparent when the following detailed description of the invention is read in conjunction with the accompanying drawings.

## BRIEF DESCRIPTION OF THE DRAWINGS

[0020] Fig. 1 is a perspective view of an embodiment of a tissue acquisition device, showing the graspers in the retracted position;

[0021] Figs. 2A is a top perspective view of the acquisition head of the device of Fig. 1;

[0022] Fig. 2B is a perspective view of the acquisition head, taken in longitudinal cross-section, of the acq uisition head of the device of Fig. 2A.

[0023] Fig. 3 is a perspective view of the acquisition head, showing one of the graspers in the deployed position;

[0024] Fig. 4 is a perspective view similar to Fig. 3, showing both graspers in the deployed position;

[0025] Figs. 5A - 5C are a series of perspective views ofthe distal portion of the acquisition head, showing both graspers in retracted, partially deployed, and fully deployed positions, respectively.

[0026] Fig. 6 is a perspective view of the proximal portion of the acquisition head, with the graspers in the retracted position.

[0027] Fig. 7 is a perspective view similar to Fig. 7 but with the housing eliminated to permit viewing of the graspers and associated features.

[0028] Fig. 8 is a perspective view of a distal portion of the acquisition head, with the graspers in the retracted position.

[0029] Fig. 9 is a perspective view of the proximal portion of the acquisition head, with the graspers in the deployed position.

[0030] Fig. 10 is a perspective view similar to Fig. 10 but with the housing eliminated to permit viewing of the graspers and associated features.

[0031] Fig. 11 is a perspective view of a distal portion of the acquisition head, with the graspers in the deployed position.

[0032] Fig. 12 is a top plan view of a proximal portion of the acquisition head, with the proximal portion of the housing shown in cross-section to permit viewing of the cable channels.

[0033] Figs. 13A - 13C are a sequence of transverse cross-section views of the acquisition head, schematically illustrating use of the device to acquire and grasp tissue. Fig. 13D illustrates use of a tissue fastening device to secure the layers of tissue acquired and grasped in Figs. 13A - 13C.

## DETAILED DESCRIPTION OF THE INVENTION

**[0034]** The present application describes a device and method for acquiring two or more areas or pinches of tissue and for supporting the acquired tissue until it has been fastened together using staples or other fasteners, or treated in some other way. Generally speaking, the disclosed device operates to acquire tissue using vacuum pressure, and to then hold or retain the acquired tissue in place using mechanical graspers. The device and method may be used in to procedure for joining tissue areas together to form tissue structures within, to remodel, or to partition a body cavity, hollow organ or tissue tract. The application will discuss the device and method in connection with use in the stomach for formation of plications such as for stomach partitioning or other purposes, although they may be used for applications other than stomach remodeling or partitioning.

**[0035]** Referring to Fig. 1, an exemplary embodiment of a tissue acquisition device 100 includes a tissue acquisition head 10 positioned at the distal end of an elongate shaft 12. The shaft is of sufficient length to allow it to be advanced into the target body cavity (e.g. stomach) through a natural orifice (e.g. the mouth) in a human. While not shown in the drawing, the device 100 preferably includes articulation features allowing the head to be articulated to facilitate positioning of the head relative to target tissue.

**[0036]** Acquisition head 10 comprises a housing having a pair of side-by-side vacuum chambers 14a, 14b. One or more vacuum sources 16 are fluidly coupled to the vacuum chambers 14a, 14b, preferably in a manner that allows a user to selectively apply vacuum pressure to the vacuum chambers 14a, 14b at different times. As shown in Fig. 2B, head 10 includes a pair of vacuum channels 15, each fluidly coupled with a plurality of holes 17 extending into an associated one of the vacuum chambers 14a, 14b. Vacuum pressure is applied to the vacuum channels 15 via openings 19 (see also Fig. 6) in the head 10. Each opening 19 is continuous with a lumen or channel through the shaft 12 to the vacuum source. As can be appreciated from Fig. 1, shaft 12 carries vacuum lines between the vacuum source and the vacuum channels in the device and cables operatively connecting a cable actuator to the device, for controlling the operation of the retention elements in the device. The tissue acquisition device and shaft by which operation of the device can be controlled from outside the body is referred to herein, collectively, as a tissue acquisition system.

[0037] Controls on the vacuum source 16 or the shaft 12 allow a user to select which vacuum chamber 14a, 14b is to receive vacuum pressure at any given moment in the procedure. For example, each opening 19 in the handle may be continuous with a dedicated lumen in the shaft, where each lumen has a valve that may be opened to apply vacuum through that lumen to the associated one of vacuum chambers 20a, 20b. Alternatively, each opening 19 in the handle may be continuous with a dedicated lumen that is connected to its own source of vacuum pressure, so that vacuum pressure to a given vacuum chamber is initiated by activating the appropriate vacuum source.

[0038] The acquisition head further includes retention elements that function to mechanically engage a portion of the tissue that has been acquired by the vacuum chamber. Referring to Figs. 3 and 4, channels 18 within the acquisition head 10 house advanceable and retractable graspers 20a, 20b that function as retention elements in the illustrated embodiment. Each grasper 20a, 20b shown includes a plurality of arcuate fingers 26 that extend into a corresponding one of the vacuum chambers 14a, 14b. In alternate embodiments, the graspers can have a variety of other configurations, including those that do not extend into the vacuum chamber but that instead clamp an outer section of the tissue drawn into the chamber against the exterior surface of the acquisition head.

[0039] A least one actuator 22 is positioned on the handle 12 (Fig. 1) allowing for independent control of each of the graspers 20a, 20b. During the course of a procedure, a user may use the actuator(s) 22 to first deploy the grasper 20b as in Fig. 3 to engage tissue drawn into vacuum chamber 14b, and to later advance the graspers 20a (Fig. 4) to engage a second pinch of tissue subsequently drawn into the vacuum chamber 14a.

[0040] Figs. 5A - 5C illustrate advancement of the graspers 20a, 20b from the retracted position (Fig. 5A), to a semi-deployed position (Fig. 5B), to a fully deployed position (Fig. 5C). Each of the fingers 26 includes a curved guide channel 28 (most visible in Figs. 5B and 5C). A pair of guide pins 30 (only the distal ends of which are visible in Figs. 5A - 5C) extend longitudinally through each side of the head 10. Each of the guide pins 30 extends through the guide channels on that side of the head 10. As the fingers 26 move to the deployed position, their guide channels slide over the guide pins 30, ensuring that the free ends of the fingers track downwardly into the corresponding vacuum chamber.

[0041] Figs. 5A - 5C further illustrate movement of drive links 24, which pivot laterally outwardly to drive the graspers 20a, 20b to the deployed position. The mechanism for driving the links 24 for advancing and retracting the graspers 20a, 20b will next be described with respect to Figs. 6 - 11. Attention is first directed to Figs. 6 and 10, in which the housing of the head 10 has been omitted to permit clear viewing of the graspers and associated features. A longitudinally extending pin 32 connects the fingers 26 of each grasper 20a, 20b. Each of the drive links 24 has a first end coupled to the distal end of one of the pins 32, and a second end coupled to an arm rotator pin 34 which is oriented longitudinally relative to the housing.

[0042] A cable link 38 is attached to the proximal end of the arm rotator pin 34, at pivot location 36. Cable link has ends pivotable about the pivot location 36. A spring 40 extends between one end of the cable link 38 and a pin 42 mounted to the housing of the head 10. The other end of the cable link 38 includes an end pin 46 to which a pull cable 44 is secured. Referring to Fig. 12, a pull cable 44 extends from end pin 46, around a cylindrical cable guide 48, into a cable channel 50 (also see Fig. 6) and through the shaft 12 (Fig. 1) where it is coupled to actuator 22.

[0043] To deploy one of the graspers 20a, 20b, actuator 22 is manipulated to pull the cable 44 associated with the grasper to be deployed. Tension on the cable 44 rotates the cable link 38 about pivot 36 from the position shown in Fig. 7 to the position shown in Fig. 10. Rotation of the cable link 38 rotates the arm rotator pin 34, thus causing link 24 to pivot laterally outwardly from the position shown in Fig. 8 to the position shown in Fig. 11. This movement of the link 24 pivots the pin 32 laterally outwardly, and thereby advances the attached fingers 26 to the deployed position. Cable link 38, arm rotator pin 34, and link 24 thus provide linkage operatively connected to retention element for moving the retention element between an open or retracted position (Fig. 7) and a closed position (Fig. 11) in which the fingers of the retention element are positioned to allow tissue to be drawn into the associated chamber when a vacuum is applied thereto, and to retain the tissue within that chamber, when vacuum is released in that chamber.

[0044] The spring 40 serves to bias the cable link 38 in the position shown in Fig. 7, thus keeping the graspers 20a, 20b biased in the retracted position. It can be seen by comparing Figs. 7 and 10 that when the cable link 38 is rotated by the cable 44, the spring expands from

its resting position to a position in tension. When the actuator 22 is caused to release the tension on the cable 44, the spring returns to its resting state, thereby returning the graspers to the retracted position.

**[0045]** Figs. 13A - 13D schematically illustrate use of the acquisition device to place two two-layer folds of tissue in apposition for fastening together using a tissue fastener such as a stapler, clip applier, suture device etc, although the acquisition device may be used for procedures as well.

**[0046]** During use of the acquisition device, the head 10 of the device 100 is introduced into a patient (e.g. into the stomach through an endogastric overtube) and advanced towards tissue to be acquired. A first one of the vacuum chambers 14b is positioned adjacent the target tissue, and the vacuum source is activated relative to that chamber, thus drawing the target tissue into the chamber as shown in Fig. 13A. Once a sufficient volume of tissue has been drawn into the chamber, the actuator is used to drive the grasper 20b into the chamber 14b as shown in Fig. 13B. When the tissue has been securely acquired by the first grasper, vacuum pressure in chamber 14b is released and the vacuum head (with the first tissue pinch securely engaged in chamber 14b) is repositioned to position the vacuum chambers 14a at a second area of target tissue. Vacuum is again initiated to draw tissue into the second chamber 14a. After the desired volume of tissue has been drawn into the chamber 14a, grasper 20a is advanced to retain the tissue within chamber 14a. At this time the vacuum may again be released.

**[0047]** Once tissue has been secured in each chamber as shown in Fig. 13C, the acquisition head 10, with the two tissue pinches retained by its graspers, is manipulated to place the layers L of the tissue pinches or folds P in tension. A fastening instrument 60 is positioned as shown in Fig. 13D to drive fasteners transversely through the four layers of tissue comprising the acquired tissue pinches. Fastening instrument 60 may be a stapler having a cartridge 62 and anvil 64. Any of a number of known devices for stapling or otherwise fastening two or more tissue folds together may be employed in fastening the acquired tissue folds in the present invention. One exemplary stapler is described in co-owned patent application USSN 12/268,404 for MULTI-FIRE STAPLING SYSTEMS AND METHODS FOR DELIVERING ARRAYS OF STAPLES, and filed on the same date as the present application. This stapler is designed for multiple staple-array firings, allowing multiple tissue regions to be acquired and

fastened, each with a plurality of staples, without having to withdraw and reload the stapler between different tissue acquisition and stapling operations. The tissue acquisition device may be part of a tissue reconfiguration or partitioning system that also includes the disclosed stapler, or any of a variety of mechanisms for applying a fastening element (e.g.clips, sutures, staplers, two-part fasteners etc.) to the acquired tissue.

**[0048]** It should be recognized that a number of variations of the above-identified embodiments will be obvious to one of ordinary skill in the art in view of the foregoing description. Moreover, features of the disclosed embodiments may be combined with one another and with other features (including those taught in the prior applications referenced herein) in varying ways to produce additional embodiments. Accordingly, the invention is not to be limited by those specific embodiments and methods of the present invention shown and described herein. The applications and methods listed are not limited to the treatment of diseases or procedures listed. Modifications of the above described methods and tools and variations of this invention that are obvious to those of skill in the art are intended to be within the scope of this disclosure.

**[0049]** Any and all patents, patent applications and printed publications referred to above, including those relied upon for purposes of priority, are incorporated herein by reference.

IT IS CLAIMED:

1. A tissue acquisition device for use in acquiring tissue from remote regions within a hollow organ, for purposes fastening the acquired regions to one another, comprising:

(a) an acquisition head defining first and second side-by-side tissue-acquisition chambers.

(b) a vacuum channel communicating with each of said chambers, through which a vacuum may be independently applied to the first and second chambers, such that when the acquisition head is placed against a first wall region within the organ, and vacuum is applied to the first chamber, a portion of the wall region is drawn into the first chamber,

(c) associated with the first chamber, a first retention element, and

(d) a first linkage operatively connected to the retention element for moving the same between open and closed positions in which the retention element is positioned to allow tissue to be drawn into the chamber when a vacuum is applied thereto, and to retain tissue drawn into the chamber, when vacuum is released from the first chamber, respectively,

wherein the tissue acquisition device, with tissue retained in the first chamber by the retention element, can be moved to a second tissue region within the organ to draw a second target tissue into the second chamber by application of a vacuum to the second chamber, such that the two tissue regions are configured as side-by-side tissue folds that can be fastened together.

2. The acquisition device of claim 1, wherein the retention element includes a plurality of fingers which in the second position extend at least partially into the vacuum chamber to retain tissue drawn into the acquisition chamber.

3. The acquisition device of claim 1, wherein the retention element is biased toward its open position, and moveable against the bias to its closed position.

4. The acquisition device of claim 1, which further includes, associated with the second vacuum chamber, a second retention element, and a second linkage operatively connected to the second retention element for moving the same between open and closed positions in which the retention element is positioned to allow tissue to be drawn into the second

chamber when a vacuum is applied thereto, and to retain tissue drawn into the second chamber, when vacuum is released from the first chamber, respectively.

5. The acquisition device of claim 4, wherein the first and second retention elements are independently moveable between their open and closed positions.

6. The acquisition device of claim 4, further including an elongate flexible shaft having a proximal end and a distal end, the acquisition head being positioned on the distal end of the elongate shaft, the shaft being proportion to extend transorally in a human subject, with the distal end in a body cavity to be treated and with the proximal end external to the human subject, and said shaft carrying one or more vacuum lines connected to said vacuum channels and one or more cables operatively connected to said linkages, for controlling the positions of the associated retention elements.

7. A tissue attachment system for use in acquiring tissue from remote regions within a hollow internal organ, for purposes fastening the acquired regions to one another, comprising:

(a) an acquisition head defining first and second side-by-side tissue-acquisition chambers,

(b) a vacuum channel communicating with each of said chambers, through which a vacuum may be independently applied to the first and second chambers, such that when the acquisition head is placed against a first wall region of the internal organ, and vacuum is applied to the first chamber, a portion of the wall region is drawn into the first chamber,

(c) associated with the first chamber, a first retention element,

(d) a first linkage operatively connected to the retention element for moving the same between open and closed positions in which the retention element is positioned to allow tissue to be drawn into the chamber when a vacuum is applied thereto, and to retain tissue drawn into the chamber, when vacuum is released from the first chamber, respectively, wherein the tissue acquisition device, with tissue retained in the first chamber by the retention element, can be moved to a second tissue region within the organ to draw a second target tissue into the second chamber by application of a vacuum to the second chamber, such that the two tissue regions are configured as side-by-side tissue folds that can be fastened together. and

(e) an elongate flexible shaft having a proximal end and a distal end at which the tissue-acquisition head is carried, the shaft being proportion to extend transorally in a human subject, with the distal end in a body cavity to be treated and with the proximal end external to the human subject, and said shaft carrying one or more vacuum lines connected to said vacuum channels and one or more cables operatively connected to said linkages, for controlling the positions of the associated retention elements.

8. The system of claim 7, which further includes a stapler for stapling together a pair of tissue folds formed by the capture of first and second tissue regions in said first and second chambers, respectively.

9. A method of fastening remote tissue regions of a hollow organ to one another, comprising

(i) transorally accessing the interior of the organ with an acquisition head defining first and second side-by-side tissue-acquisition chambers,

(ii) placing the acquisition head against a first tissue region within the hollow organ;

(iii) applying a vacuum to the first, but not the second, acquisition chamber, to draw a portion of the first tissue regions into the first chamber;

(iv) mechanically capturing the portion of the first tissue region in the first acquisition chamber,

(v) positioning the acquisition head, with the first captured tissue portion, against a second tissue region within the hollow organ,

(vi) before or after said positioning, releasing vacuum at the first acquisition chamber and applying vacuum to the second chamber,

(vii) by steps (v) and (vii) drawing a portion of the second tissue region into the second tissue-acquisition chamber,

(viii) mechanically capturing the portion of the second tissue region in the second acquisition chamber, wherein the two captured tissue regions form two tissue folds terminating at the acquisition device,

(ix) fastening the two tissue folds together; and

(x) releasing the fastened tissue folds from the acquisition device.

10. The method of claim 9, wherein mechanically capturing tissue in steps (iv) and (viii) includes moving a retention element containing a plurality of fingers into a position at which the fingers engage the tissue region within the associated acquisition chamber.

11. The method of claim 9, wherein fastening the two tissue folds together in step (ix) includes placing the folds between confronting circular faces of a staple holder and anvil and forming an annular array of staples through the two folds.

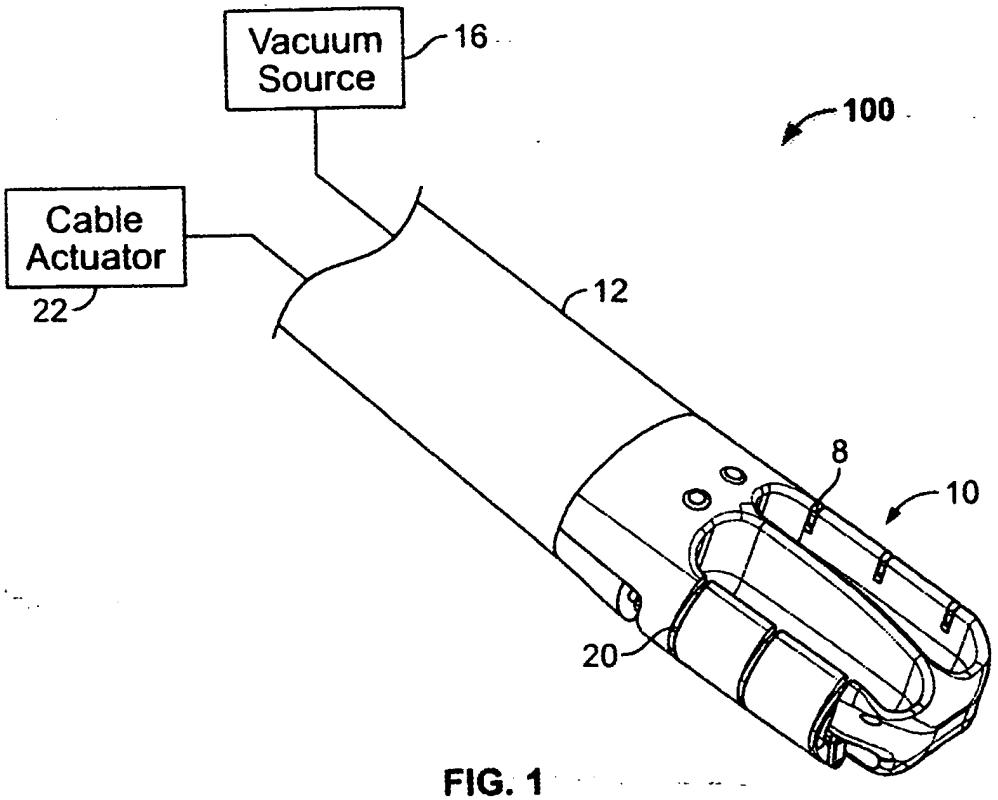
Vacuum Source
16
100
Cable Actuator
22
12
8
10
20

FIG. 1

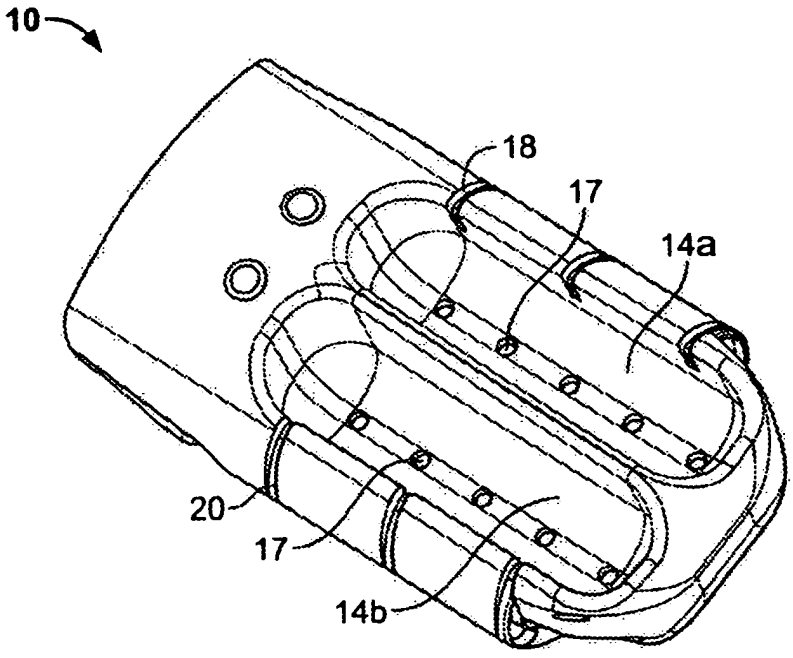
10
18
17
14a
20
17
14b

FIG. 2A

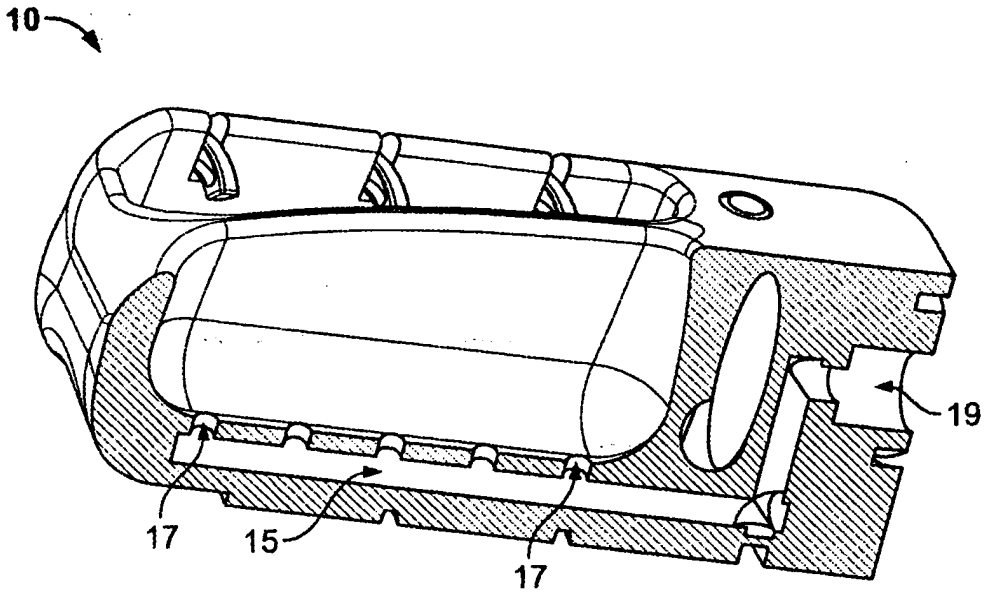


FIG. 2B

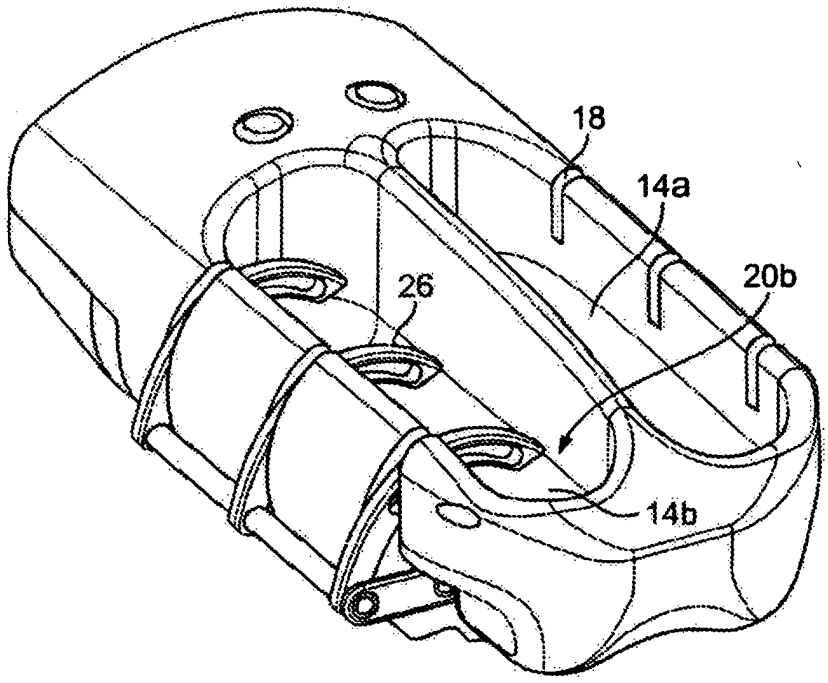


FIG. 3

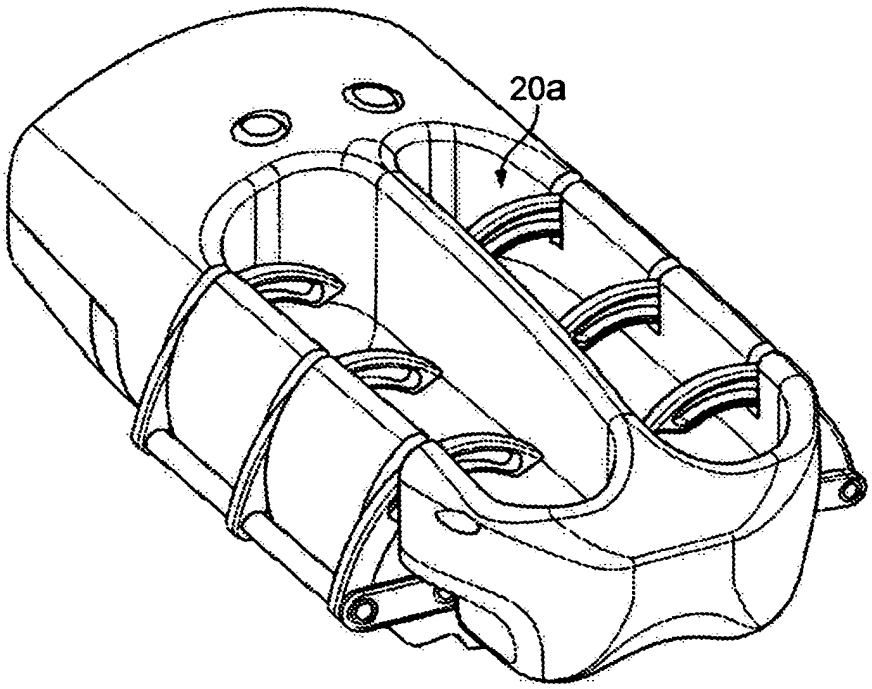


FIG. 4

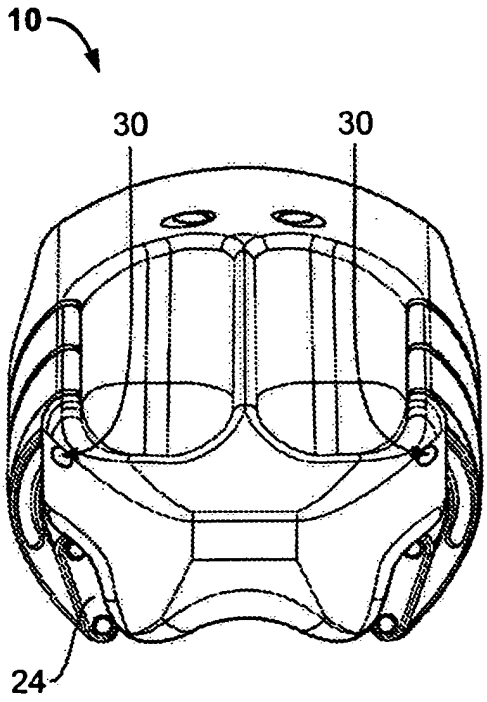


FIG. 5A

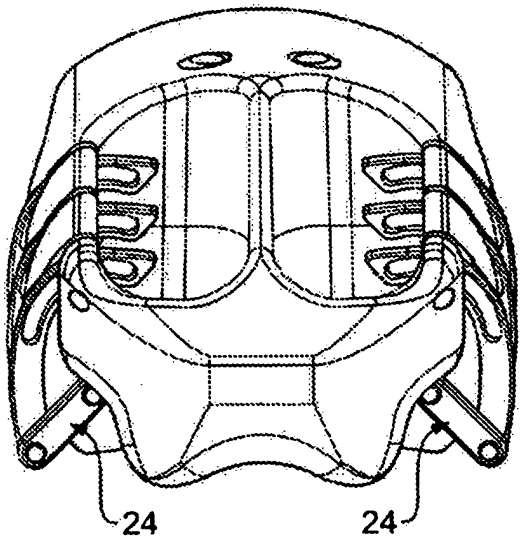


FIG. 5B

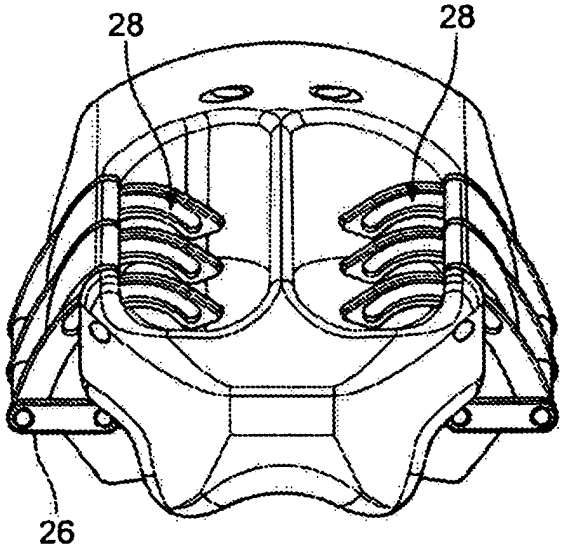


FIG. 5C

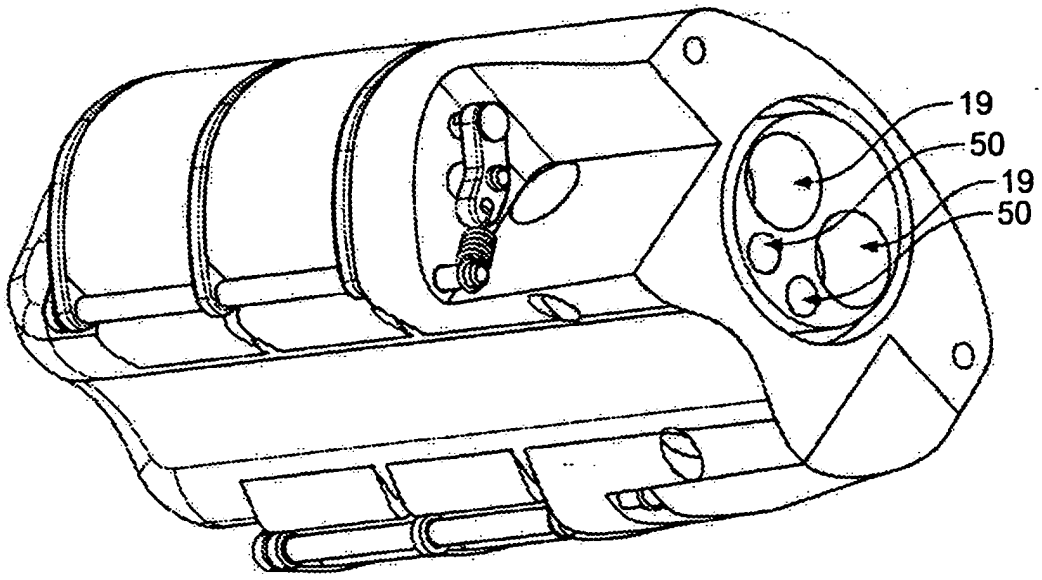


FIG. 6

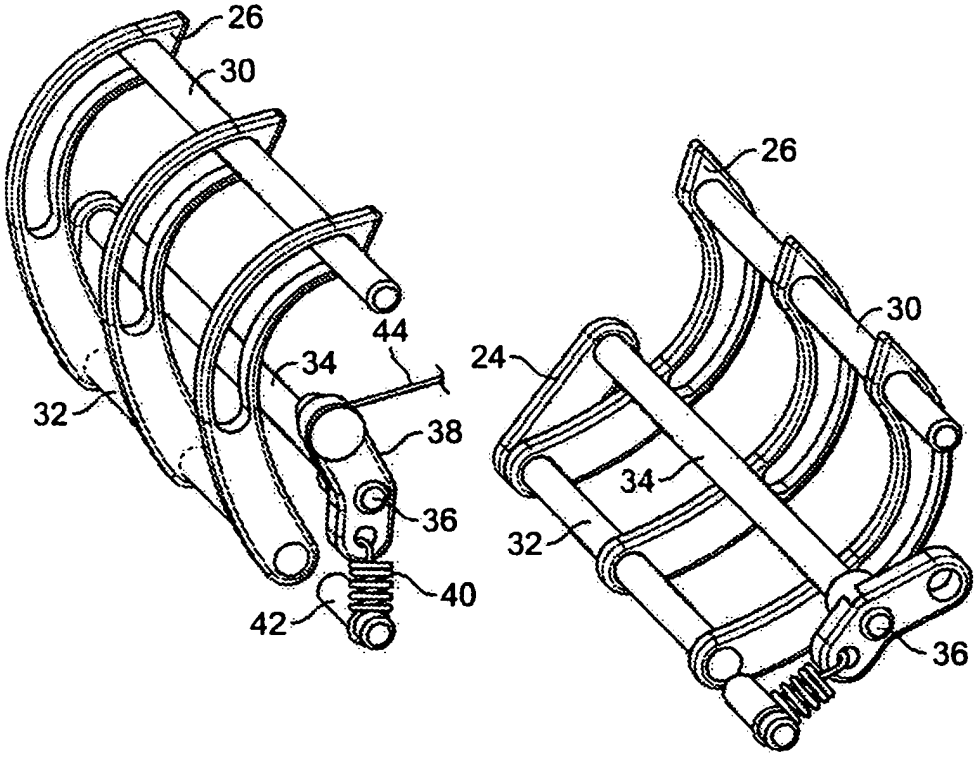


FIG. 7

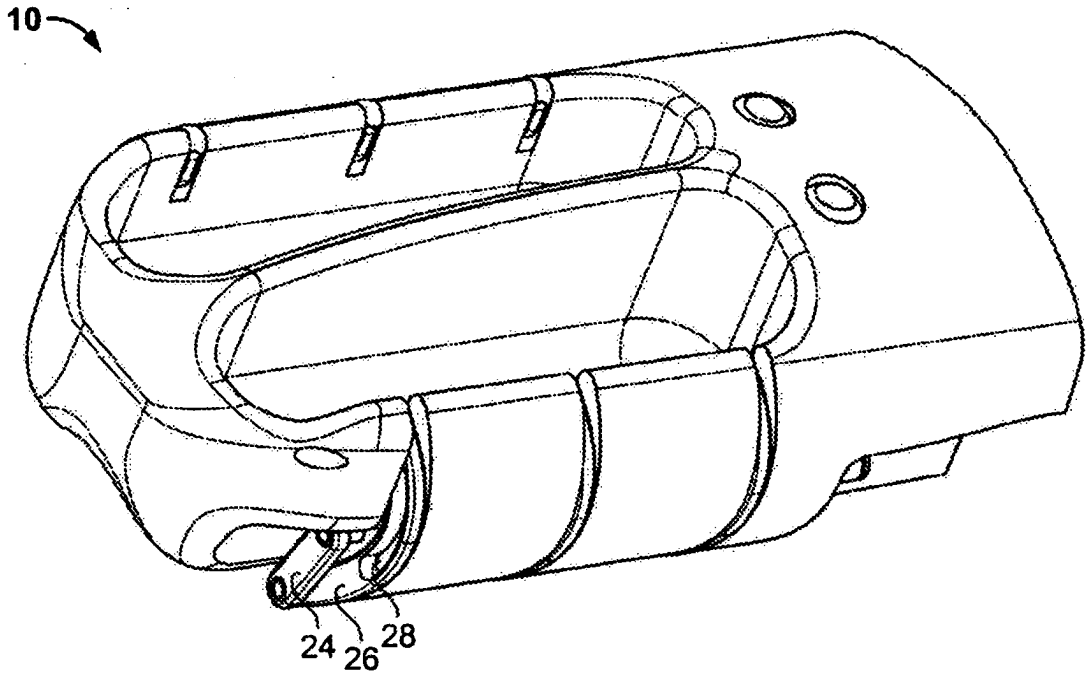


FIG. 8

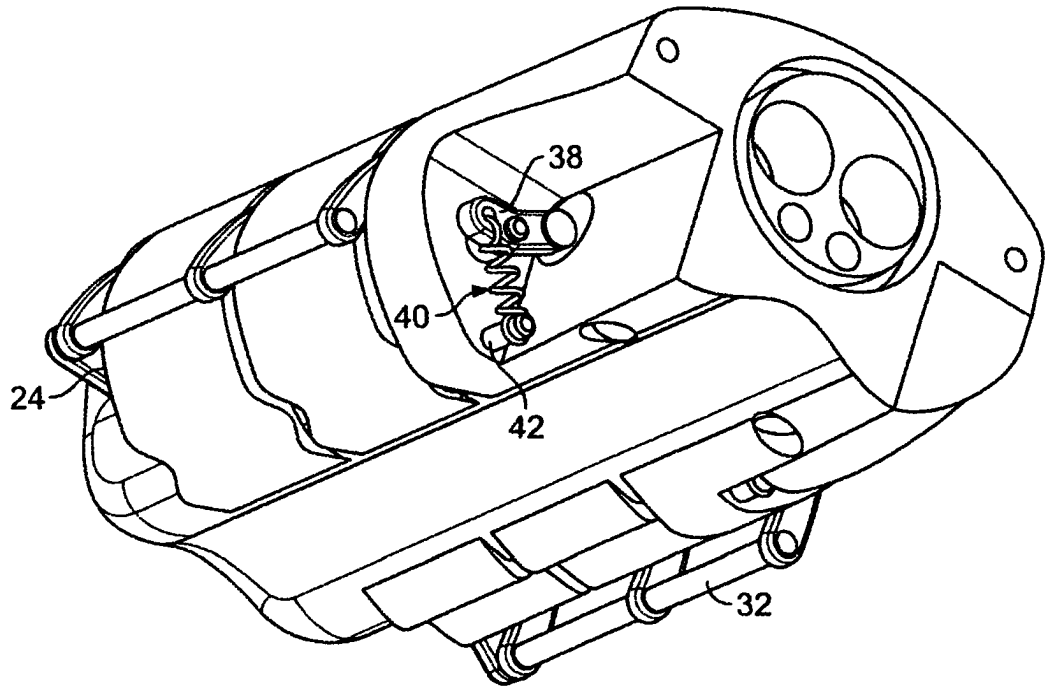


FIG. 9

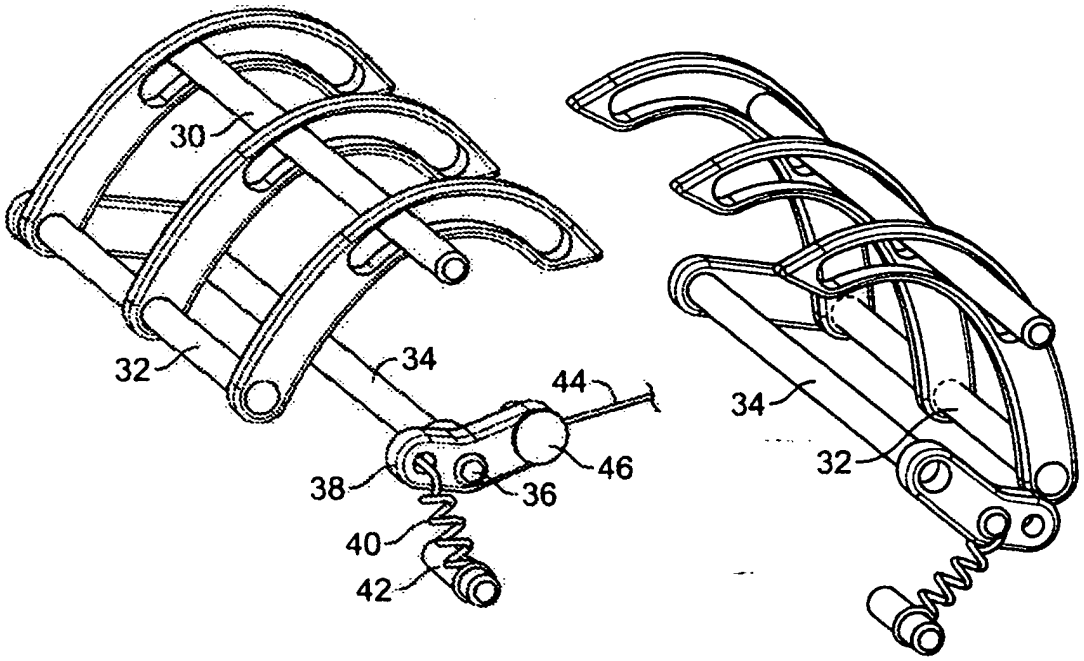


FIG. 10

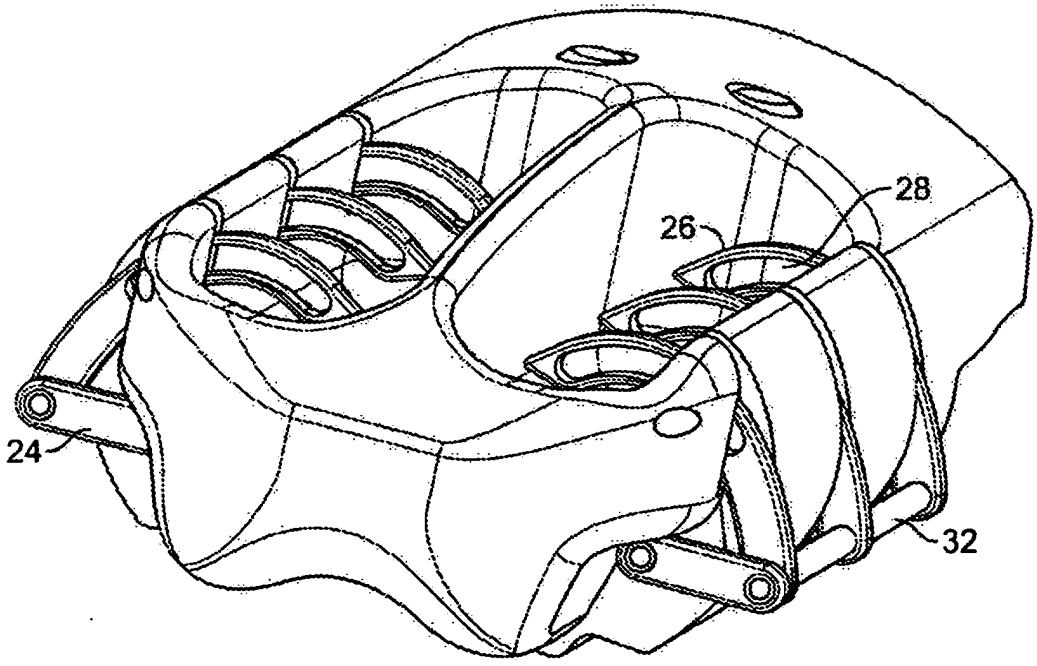


FIG. 11

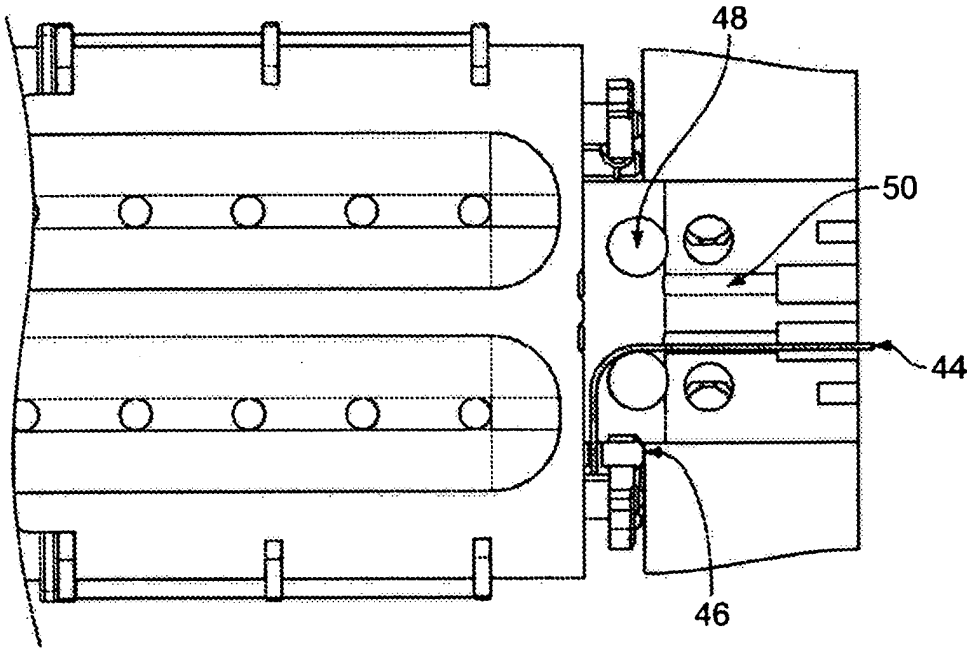


FIG. 12

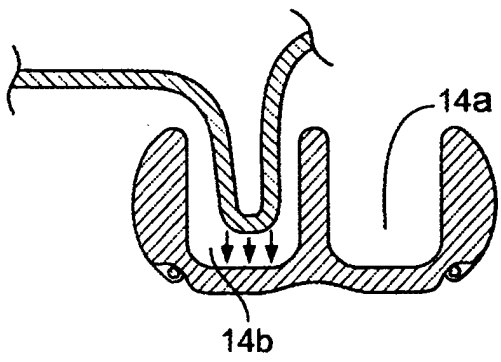


FIG. 13A

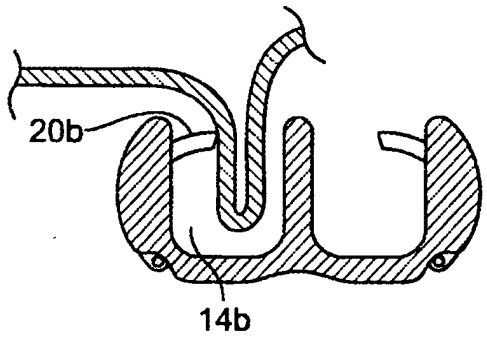


FIG. 13B

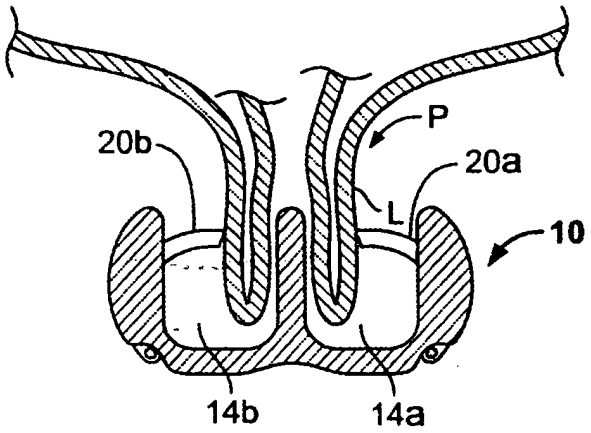


FIG. 13C

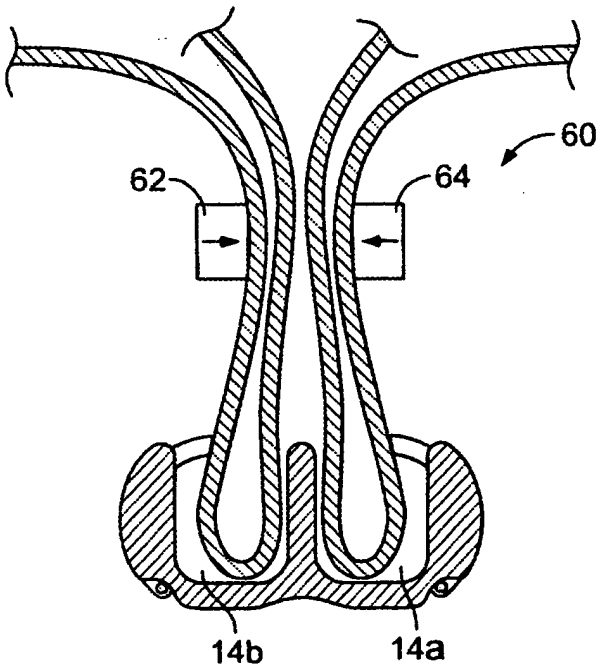


FIG. 13D

# INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2009/063925

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61B 17/04 (2010.01)
USPC - 606/144
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC(8) - A61B 17/00, 17/03, 17/04 (2010.01)
USPC - 606/144, 153

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
PatBase, Google Patents

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| X | US 2003/0208209 A1 (GAMBALE et al) 06 November 2003 (06.11.2003) entire document | 1-2, 4-10 |
| Y | | 3, 11 |
| Y | US 2007/0219571 A1 (BALBIERZ et al) 20 September 2007 (20.09.2007) entire document | 3, 11 |

☐ Further documents are listed in the continuation of Box C. ☐

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

| Date of the actual completion of the international search | Date of mailing of the international search report |
|---|---|
| 28 December 2009 | 12 JAN 2010 |
| Name and mailing address of the ISA/US<br>Mail Stop PCT, Attn: ISA/US, Commissioner for Patents<br>P.O. Box 1450, Alexandria, Virginia 22313-1450<br>Facsimile No. 571-273-3201 | Authorized officer:<br>Blaine R. Copenheaver<br>PCT Helpdesk: 571-272-4300<br>PCT OSP: 571-272-7774 |

Form PCT/ISA/210 (second sheet) (July 2009)